IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9032

Bartle, J. March 26, 2013

Jeannette Pearson ("Ms. Pearson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. George Pearson, Ms. Pearson's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Gregory R. Boxberger, M.D., F.A.C.C. Based on an echocardiogram dated October 29, 1997, Dr. Boxberger attested in Part II of Ms. Pearson's Green Form that claimant suffered from moderate mitral regurgitation and an abnormal left atrial dimension.

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3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $399,744.[4]

In the report of claimant's echocardiogram, the reviewing cardiologist, Terry A. Grainger, M.D., F.A.C.C., noted that "[m]oderate mitral regurgitation is present." Dr. Grainger, however, did not specify a percentage as to claimant's level of mitral regurgitation. Dr. Boxberger also completed a report of claimant's echocardiogram, wherein he stated that claimant had moderate mitral regurgitation of 33%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement s I.22.

In January, 2004, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for Dr. Boxberger's finding that claimant had moderate mitral regurgitation. She explained that claimant's "RJA/LAA is less than 20%."

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust disputes that claimant has an abnormal left atrial dimension, which is one of the complicating factors needed for a Level II claim, we need not resolve this issue given our determination with respect to claimant's level of mitral regurgitation.

Based on Dr. Wang's findings, the Trust issued a post-audit determination denying Ms. Pearson's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant submitted the declarations of Roger W. Evans, M.D., F.A.C.P., F.A.C.C., and Dan A. Francisco, M.D., F.A.C.C. In his declaration, Dr. Evans stated:

> The claimant's echocardiogram of 10/29/97 shows "moderate" mitral valve regurgitation with a RJA/LAA ratio of approximately 33%. In my opinion, the attesting physician had a "reasonable medical basis" to conclude that the echocardiogram tape in question shows "moderate" mitral valve regurgitation ....

In his declaration, Dr. Francisco stated:

> The claimant's echocardiogram of 10/29/97 shows "moderate" mitral valve regurgitation with a RJA/LAA ratio of 33%. In my opinion, the attesting physician had a "reasonable medical basis" to conclude that the echocardiogram tape in question shows "moderate" mitral valve regurgitation ....

Ms. Pearson argued that there was a reasonable medical basis for Dr. Boxberger's representation of moderate mitral regurgitation because four cardiologists - Dr. Boxberger, Dr. Evans, Dr. Francisco, and Dr. Grainger - agreed that she had moderate mitral regurgitation. In addition, Ms. Pearson contended that

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Pearson's claim.

the standard in show cause is whether there is a reasonable medical basis for the attesting physician's representation of moderate mitral regurgitation, not whether claimant actually has moderate mitral regurgitation. Finally, claimant asserted that the auditing cardiologist substituted her personal opinion for her attesting physician's opinion, rather than apply the reasonable medical basis standard.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Wang submitted a declaration again concluding that claimant had mild mitral regurgitation. Dr. Wang explained:

> I also observed that Claimant's level of mitral regurgitation is clearly under 20% (the regurgitant jet area is 3.0 cm^2 and the underestimated left atrial area is 17 cm^2). Indeed, it appears that the TEE underestimates Claimant's left atrial area given the lack of full views of the LAA available on Claimant's TEE.
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> Moreover, Claimant's TEE lacks routine modalities which could have been used to confirm the level of mitral regurgitation, such as measurements of PISA and pulmonary vein flow reversal.

The Trust then issued a final post-audit determination, again denying Ms. Pearson's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the Court for issuance of an Order to show cause why Ms. Pearson's claim should be paid. On

December 9, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4234 (Dec. 9, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response on the Special Master. The Trust submitted a reply on February 3, 2005, and claimant submitted a sur-reply on February 18, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[6] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the Court. The Show Cause Record and Technical Advisor Report are now before the Court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposition positions" is proper. Id.

that she has moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Pearson repeats the arguments she made in contest. In addition, claimant argues that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and the auditing cardiologist. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Pearson contends that if the Trust's auditing cardiologist or Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA by an attesting physician is medically reasonable.

In response, the Trust argues that inter-reader variability does not establish a reasonable medical basis for Dr. Boxberger's representation of moderate mitral regurgitation because Dr. Wang did not simply disagree with the representation. Rather, she found that there was no reasonable medical basis for the representation and identified specific deficiencies in the

echocardiogram. The Trust also contends that the opinions of claimant's physicians do not establish a reasonable medical basis for her claim because none of them addresses the deficiencies Dr. Wang identified, namely, that the echocardiogram appears to underestimate Ms. Pearson's LAA given the lack of full views and the lack of routine modalities.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there is no reasonable medical basis for the attesting physician's representation that claimant has moderate mitral regurgitation. Dr. Vigilante explained:

> I reviewed the Claimant's echocardiogram of October 29, 1997.... This was a typical transesophageal echocardiogram with the usual TEE views obtained. However, color Doppler evaluation was below quality because of high gain artifact....
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> Visually, mild centrally located mitral regurgitation was noted. This was a thin jet that reached the mid portion of the left atrium. I digitized those cardiac cycles in which the mitral regurgitation jet could be best identified. I then determined the RJA and LAA on several representative cardiac cycles. The largest representative RJA at minus 5 degrees was 3.8 cm2. The largest RJA at 98 degrees was 3.1 cm2. I determined that the LAA was 27.1cm2. This correlates with an enlarged left atrial dimension. Therefore, the largest representative RJA/LAA ratio was 14%. The RJA/LAA ratio never approached 20%. Most of the RJA/LAA ratios were less than 10%.
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> ....
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> In response to Question 1, there is no reasonable medical basis for the Attesting Physician's answer to Green Form Question

> C.3.a. That is, the echocardiogram of attestation demonstrated mild mitral regurgitation with comments as noted above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability when appropriate measurements of the RJA and LAA are performed.

In response to the Technical Advisor Report, claimant argues the Technical Advisor must have substituted his own personal opinion on the issue of mitral regurgitation because it "defies logic" to say that a conclusion arrived at by four highly qualified physicians is not supported by a reasonable medical basis.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately respond to the findings of the auditing cardiologist and the Technical Advisor. Dr. Wang reviewed claimant's echocardiogram and determined that claimant had only mild mitral regurgitation because the echocardiogram underestimated claimant's LAA. Dr. Vigilante also reviewed claimant's echocardiogram and determined that it demonstrated only mild mitral regurgitation when properly measured.[7] Neither claimant nor her experts identified any particular error in the conclusions of the auditing cardiologist and Technical Advisor.

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7. For these reasons as well, we reject claimant's argument that the auditing cardiologist and the Technical Advisor substituted their own personal opinion rather than properly apply the reasonable medical basis standard. To the contrary, they identified specific deficiencies with Dr. Boxberger's representation that claimant has moderate mitral regurgitation.

Mere disagreement with the auditing cardiologist and Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

We also disagree with claimant that the opinions of her experts provide a reasonable medical basis for the attesting physician's Green Form representation that Ms. Pearson has moderate mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating the echocardiogram setting; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history: and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Wang found that the echocardiogram underestimated claimant's LAA and Dr. Vigilante determined "the color Doppler evaluation was below quality because of high gain

artifact." Such unacceptable practices, which claimant does not adequately refute, cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Pearson had moderate mitral regurgitation also is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that claimant's echocardiogram demonstrates an RJA/LAA of no more than 14% and that most of the RJA/LAA ratios were less than 10%. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by ± 15% would allow a claimant to recover benefits with an RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.[8]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral

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8. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability when appropriate measurements of the RJA and LAA are performed."

regurgitation. Therefore, we will affirm the Trust's denial of Ms. Pearson's claim for Matrix Benefits and the related derivative claim submitted by her spouse.